I. REMARKS

The final Office Action dated December 3, 2008, has been received and carefully noted. The following remarks are submitted as a full and complete response thereto.

Claims 1-3 and 5-42 are pending in the application. Claims 3, 10-18 and 21-42 are withdrawn.

No amendments to the claims or specification are made at this time.

Claims 1, 2, 5-9, 19 and 20 were rejected under 35 U.S.C. §103 (a), as being unpatentable over Tsuru et al. (EP 0 376 331) in view of Holmberg et al. (WO 01/66088). Applicants traverse the rejection.

Claim 1 of the presently claimed invention is directed to a "solid drug delivery composition comprising one or more NO-donating Non Steroidal Antiinflammatory Compound(s) (NO-donating NSAID(s)) absorbed into porous particles, wherein the porous particles comprise a member selected from the group consisting of: dibasic calcium phosphate, anhydrous; microcrystalline cellulose; pregelatinised starch; calcium silicate; magnesium aluminometasilicate; and mixtures thereof" (emphasis added). Claims 2, 5-9, 19, and 20 depend from independent claim 1.

Applicants submit that Tsuru et al. discloses a "drug delivery granule capable of slowly releasing impregnated drug components" (page 2, lines 7-8). Applicants submit that although Tsuru et al. discloses that the granules can be "porous granules of a calcium phosphate compound having a Ca to P (Ca/P ratio) of 1.3 to 1.8..." (page 2, lines 48-50) (emphasis added), Tsuru et al. does not teach or suggest the presently claimed invention.

Applicants submit that dibasic calcium phosphate and dibasic calcium phosphate anhydrous have the general formula of $CaHPO_4 \cdot mH_2O$, wherein $0 \geq m \geq 0.5$. Therefore, the atomic ratio of Ca to P is 1, and when m is 0, the compound is Fujicalin® (dibasic calcium phosphate anhydrous). Applicants note that "m" refers to the number of water molecules which solvate the basic calcium phosphate molecule, and therefore, even if the value of m changes, the atomic ratio of Ca/P does not change and is always 1. Applicants submit that dibasic calcium phosphate and dibasic calcium phosphate anhydrous are different than the porous granules of Tsuru et al., which have an atomic ratio of Ca to P (Ca/P ratio) of 1.3 to 1.8. Applicants submit that the term "dibasic calcium phosphate" refers to a molecule containing calcium ions (Ca^{2+}) together with hydrogen phosphate ions (HPO_4^{2-}), and the atomic ratio of Ca/P is always 1, because the two ions that form the dibasic calcium phosphate molecules are both bivalent ions.

Applicants submit that the calcium phosphate disclosed in Tsuru refers to salts containing calcium ions (Ca^{2+}), together with an orthophosphate ion (PO_4^{3-}) or pyrophosphates ($P_2O_7^{4-}$), and the atomic ratio Ca/P is always greater than 1. For example, Applicants submit that hydroxyapatite (disclosed in Example 1 of Tsuru et al.) has the formula $Ca_5(PO_4)_3(OH)$ and an atomic ratio Ca/P of 1.67, and tricalcium phosphate (disclosed in Example 3 of Tsuru et al.) has the formula $(Ca)_3(PO_4)_2$ and an atomic ratio Ca/P of 1.5.

Further, Applicants submit that Tsuru et al. also fails to teach or suggest the other porous particles of claim 1, in particular microcrystalline cellulose, pregelatinised starch, calcium silicate, and magnesium aluminometasilicate, or mixtures thereof.

Applicants submit that Holmberg et al. does not fulfill the deficiencies of Tsuru et al. For example, Applicants submit that Holmberg et al. discloses a pharmaceutical composition in the form of an emulsion pre-concentrate, comprising one or more NO-releasing NSAIDs, one or more surfactants, and optionally an oil or semi-solid fat (page 4, lines 6-12). Holmberg et al. discloses NO-releasing naproxen (formula (Ia), page 8). However, there is no prima facie case of obviousness with the combination of Holmberg et al. with Tsuru et al.

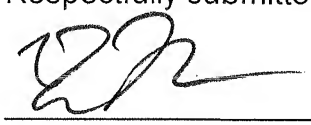
For at least the above reasons, Applicants submit that the presently claimed invention is patentable over Tsuru et al. and Holmberg et al. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 2, 5-9, 19 and 20 under 35 U.S.C. § 103(a).

II. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. **026220-00054**.

Respectfully submitted,



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